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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--------------------------------------|---------------|----------------------|---------------------------------|-----------------------|--|
| 10/713,949 | 11/13/2003 | Robert A. Farris | 4002-3445/PC295.12 | 2904 | |
| 75 | 90 12/14/2004 | | EXAM | INER | |
| Woodard, Emhardt, McNett & Henry LLP | | | REIP, DAVID OWEN | | |
| Bank One Cente Suite 3700 | er/Tower | | ART UNIT | ART UNIT PAPER NUMBER | |
| 111 Monument | Circle | | 3731 DATE MAILED: 12/14/2004 | | |
| Indianapolis, Il | N 46204-5137 | • | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|--|--|-------------|--|--|--|--|
| | Application No. | Applicant(s) | 9. | | | | |
| Office Action Summans | 10/713,949 | FARRIS ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | David O. Reip | 3731 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the (| corresponaence adare | 988 | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ti within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | mely filed ys will be considered timely. In the mailing date of this commoder (35 U.S.C. § 133). | nunication. | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 25 O | ctober 2004 and 15 November 2 | <u>:004</u> . | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | action is non-final. | | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| | x parte Quayle, 1955 C.D. 11, 4 | 55 O.G. 215. | | | | | |
| Disposition of Claims | | | | | | | |
| 4) ☐ Claim(s) <u>9-12 and 14-42</u> is/are pending in the a 4a) Of the above claim(s) <u>20-22, 29 and 34-38</u> 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) <u>9-12,14-19,23-28,30-33 and 39-42</u> is/ 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | is/are withdrawn from considerates are rejected. | tion. | | | | | |
| Application Papers | | | | | | | |
| 9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 13 November 2003 is/a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Ex | re: a)⊠ accepted or b)⊡ object drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob | ee 37 CFR 1.85(a). ojected to. See 37 CFR | 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicat ity documents have been receiv ı (PCT Rule 17.2(a)). | ion No ed in this National Sta | age | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/13/03. | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other: | | 52) | | | | |

DETAILED ACTION

Election/Restrictions

Claims 20-22, 29 and 34-38 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/25/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-27, 30-32, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Tornier (U.S. Pat. No. 4,488,543). Figs. 1-3 of Tornier show a bone fixation system having all the limitations as recited in the above listed claims, including: a curved plate 2; a first opening 6 left; a second opening 6 right (for the purpose of interpretation of the reference and this action, consider in Fig. 1 that the opening in the upper left corner of the plate will be designated "6 left," and the opening in the upper right corner of the plate will be designated "6 right."); a first fastener 3 having a first shank perimeter (tapered portion 3a being considered a portion of the shank) substantially corresponding to the first opening 6 left perimeter, and is positionable at a

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fixed angle relative to the bottom surface of the plate; a second fastener 4 (clearly seen as having a smaller shank diameter than fasteners 3) with a second shank perimeter substantially smaller than the second opening 6 right, and is inherently positionable at a plurality of angles relative to the bottom surface of the plate (if placed through the second opening 6 right); and a locking assembly (9, 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28, 33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tornier. Tornier does not specifically disclose a fusion member holdable in a position by the plate. However, it is a well established practice in the art of orthopedic surgery to insert a fusion member (or substance, such as bone cement) at a fracture site or, in the case of vertebral fusion, in the disk space(s) between two or more vertebrae that are to be fused, and then cover the fusion member with a fixation plate in order to hold the underlying bones and fusion member in intimate contact with one another to promote a successful fusion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Tornier plate in combination with a fusion member, for the reasons discussed above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-12, 14-19, 23-28, 30-33 and 39-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6,669,700 and over claims 1-79 of U.S. Patent. No. 6,152,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are either broader in scope (i.e. "generic") to the more narrow "species" claims already granted in the '700 and '927 patents, or are substantially similar in scope to the claims already granted in the '700 and '927 patents. Thus, the generic invention (e.g. the invention defined by a claim to ABC) is "anticipated" by the species (e.g. the invention defined by a claim to ABCXY) of the patented invention. Accordingly, absent a terminal disclaimer, claims 9-12, 14-19, 23-28, 30-33 and 39-42 are properly rejected under the doctrine of obviousness-type double patenting. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-4702. The examiner can normally be reached on 7 A.M.- 4 P.M. Mon-Thu and every other Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David O. Reip

Primary Examiner

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